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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,267	02/17/2004	Donald Lynn Bissett	9176R	2224

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EXAMINER	
ISSAC, ROY P	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,267	BISSETT, DONALD LYNN	
	Examiner	Art Unit	
	Roy P. Issac	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 21-29* is/are pending in the application.

4a) Of the above claim(s) *6-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5, 21-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/30/04; 6/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a continuation in part of 10/379,252, filed on 03/04/2003, now abandoned. This office action is in response to applicant's response to election/restrictions requirement filed 25 September 2006 and refilled on 05 March 2007.

Election/Restrictions

Applicant's election with traverse of the invention of Group I, claims 1-5 and 21-29 drawn to a composition comprising a hexamidine compound, a safe and effective amount of skin care active agents and a dermatologically acceptable carrier is acknowledged.

The traversal is on the grounds that treatment of materially different diseases does not meet the requirement that the product can be used in a materially different process. Applicants argue that the methods of use are connected in operation, in that the methods of use recite application of the claimed composition. However, the restriction is proper between a product and process of use as indicated in the requirement for restriction, mailed 7/25/2006. The examiner has set forth the criteria for products and processes of use of the same. (See Page 2, Last paragraph to page 3, second paragraph). A "use" can only be properly claimed as a process or method. 35 U.S.C.§§ 100(b), 101. *See Clinical Products v. Brenner,* 255 F. Supp.131., 149 USPQ 475, 477 (D.D.C 1966). *In re Thuau.* 1943 C.D. 390. Each method of treatment relates to a separate and distinct area of pharmaceutical technology. The search for all

inventions would place an undue burden on the office in view of the diversity of the medical disorders to be treated and the corresponding diversity in the field of search for each.

The search field for compositions is not coextensive with the search field for a process of using the same compositions. A reference to the compositions herein would not necessarily be a reference to the method of using the same herein. The compositions and methods of use have separate consideration as to patentability.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with

an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The restriction requirement between Inventions I and II was deemed proper and is therefore made FINAL.

Claims 6-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 25 July 2006.

Claims 1-5 and 21-29 will be examined on the merits herein.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed.

Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, and 4-16 of copending Application No. 10/152,924. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '924 application is directed to an article comprising a skin care composition comprising hexamidine, niacinamide (vitamin B3) and a carrier. The claims herein are directed to a composition comprising hexamidine, vitamin B3 and a carrier. Thus, claims 1-3 are deemed anticipated by claims 1-2 and 4-16 of the co-pending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5 and 21-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The recitations, "derivatives" in these claims render claims herein indefinite. The recitations, "derivatives" of the compounds are not clearly defined in the specification. Hence, one of ordinary skill in the art could not ascertain and interpret the metes and bounds of the patent protection desired as to "derivatives" of compounds herein. One of ordinary skill in the art would clearly recognize that derivatives of hexamidine compounds or one of the skin care actives would read on any those compounds having any widely varying groups that possibly substitute the compounds.

Any significant structural variation to a compound would be reasonably expected to alter its properties; e.g., physical, chemical, physiological effects and functions. Thus, it is unclear and indefinite as to the "derivatives" of compounds herein encompassed thereby.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or

> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Jensen et. al. (U. S. Patent No. 6,589,514; PTO-892)

Jensen et. al. discloses compositions comprising hexamidine (0-1%) and retinyl palmitate, (0-1%), a retinoid and carriers including water, seed oil and vegetable oil. The presence of water, fruit juice, glyceryl stearate, seed oil, vegetable oil and PEG-40 stearate is expected to form an emulsion in the form of a water-in-oil or oil-in-water or a combination of both. As such, claims 1-5 are deemed anticipated by Jensen et. al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 23, 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Flick et. al. (Cosmetic Additives – An industrial Guide, Pages 647-648, 652; PTO-892) further in view of Gensler et. al. (Nutrition and Cancer, 29(2), 157-162; PTO-892).

The disclosure of Jensen et. al. is discussed above in the 102 rejection. Furthermore, Jensen et. al. discloses the use of panthenol in a skin care composition.

Jensen et. al. does not expressly disclose a composition comprising vitamin B3 or panthenol in combination with a hexamidine compound and a carrier. (Column 11, Example 2, line 53-64).Jensen et. al. further discloses the use of tocopheryl acetate (Column 11, Example 2, line 58-60, Example 4, lines 43, Example 1).

Flick et. al. in his cosmetic handbook discloses that panthenol is used in skin care products as a quick deep penetrating moisturizer, that aids in tissue repair and promotes normal keratinization. (Cosmetic Additives – An Industrial Guide, Page 648, Paragraph titled "Role in skin care products"). Flick et. al. further discloses commercial sources of panthenol compounds. (Page 647). Flick et. al. further discloses commercial sources of various forms of vitamin E including α-tocopherol acetate. (Page 652) As such, panthenol and α-tocopherol acetate are considered as ingredients well known by one of ordinary skill in the arts in the cosmetic, pharmaceutical and skin care industry.

Gensler HL et. al. discloses that topical nicotinamide prevents the systemic immunosuppression and skin tumorigenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that immunoenhancement by nicotinamide results in prevention of phtocarcinogenesis. (Page 161, Column 2, second paragraph). Gensler et. al. further discloses that α-tocopherol can also

contribute to inhibition of photoimmunosuppression and photocarcinogenesis. (Page 161, Column 2, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, vitamin B3, panthenol, α-tocopherol acetate and a carrier because Jensen et. al. discloses skin care compositions comprising α-tocopherol acetate, hexamidine and discloses panthenol in skin care compositions and Flick et. al. discloses panthenol and α-tocopherol acetate as commercially available cosmetic additives and Gensler et. al. discloses that topical application of niacinamide and α-tocopherol can contribute to inhibition of photoimmunosuppression and photocarcinogenesis.

One of ordinary skill in the art would have been motivated to make a skin care composition comprising hexamidine, vitamin B3, panthenol, α-tocopherol acetate and a carrier because Jensen et. al. discloses skin care compositions comprising α-tocopherol acetate, hexamidine and discloses panthenol in skin care compositions and Flick et. al. discloses panthenol to have moisturizing properties as well as maintaining normal keratinization, and Gensler et. al. discloses that topical application of niacinamide and α-tocopherol can contribute to inhibition of photoimmunosuppression and photocarcinogenesis.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, vitamin B3, panthenol, and α-tocopherol in skin care compositions would have had beneficial effects such as moisturizing,

maintenance of keratinization and the prevention of photoimmunosuppression and photocarcinogenesis.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Gensler et. al. (Nutrition and Cancer, 29(2), 157-162; PTO-892). further in view of Mammone et. al. (WO 00/67722; PTO-892)

The disclosure of Jensen et. al. is disclosed above in the 102(b) and 103(a) rejections

Jensen et. al. does not expressly disclose the use of vitamin B3 compounds, in particular niacinamide or the use of N-acetyl glucosamine in skin care compositions.

The disclosure of Gensler et. al. is discussed above.

Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions used for exfoliation and moisturization. (Abstract, Page 2, lines 14-17).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, N-acetyl glucosamine, niacinamide and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine and Gensler et. al. discloses that topical application of niacinamide can contribute to inhibition of photoimmunosuppression and photocarcinogenesis and Mammone et. al.

discloses the use of N-acetyl glucosamine in skin care compositions as an exfoliant.

One of ordinary skill in the art would have been motivated to make a skin care composition comprising hexamidine, N-acetyl glucosamine, niacinamide and a carrier because Jensen et. al. discloses skin care compositions comprising α-tocopherol acetate, hexamidine and Gensler et. al. discloses that topical application of niacinamide can contribute to inhibition of photoimmunosuppression and photocarcinogenesis and Mammone et. al. discloses the use of N-acetyl glucosamine in skin care compositions as exfolient.

Therefore, one of ordinary skill in the art would have reasonably expected that the use of hexamidine, N-acetyl glucosamine, niacinamide and a carrier in skin care compositions would have had beneficial effects such as moisturizing, exfoliation, maintenance of keratinization and the prevention of photoimmunosuppression and photocarcinogenesis.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jensen et. al. in view of Castiel et. al. (US 2003/0176366 A1, PTO-892) .
The instant application is a CIP of 10/379,252, filed 03/04/2003. However, the'252 application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for the instant new claim 25 of this application for

CIP since the '252 application do not disclose the particular composition comprising ascorbyl glucoside recited in claim 25. Therefore, the filing date of claim 25 is deemed to be the filing date of the instant application, 02/17/2004.

The disclosure of Jensen et. al. is discussed above

Jensen et. al. does not expressly disclose the use of ascorbyl glucoside in skin care compositions.

Castiel et. al. discloses that ascorbic acid compounds, in particular ascorbyl glucoside increases epidermal lipogenesis. (Column 2, Paragraphs 22-25, Example 1, Paragraphs 57-62; Page 4, Column 1, Table) Castiel further exemplifies cosmetic compositions comprising ascorbyl glucoside (Page 4, Column 2, Example 3).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a skin care composition comprising hexamidine, a retinoid, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, carriers and a retinoid and Castiel et. al. discloses the use of ascorbyl glucoside in skin care compositions to increase epidermal lipogenesis.

One of ordinary skill in the art would have been motivated to make a skin care composition comprising hexamidine, ascorbyl glucoside and a carrier because Jensen et. al. discloses skin care compositions comprising hexamidine, a retinoid, and a carrier and Castiel et. al. discloses that the use of ascorbyl glucoside in skin care compositions increases epidermal lipogenesis.

Therefore, one of ordinary skill in the art would have reasonably expected that the use ascorbyl glucoside in a skin care composition comprising hexamidine, a retinoid and a carrier would result in substantially similar or improved skin care composition.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy P. Issac whose telephone number is 571-272-2674. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

4/9/07

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